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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Akira Sekine

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DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP

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EXAMINER

GAKH, YELENA G

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,477	SEKINE ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-17 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. RCE and Amendment filed on 03/08/06 are acknowledged. Claims 1-12, 14-17 and 39 are pending in the application.

Response to Amendment

2. In response to the amendment rejection of the pending claims under 35 U.S.C. 112, second paragraph, is slightly modified. Rejection over the prior art remains the same.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12, 14-17 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "wherein at least some of said controlled substances are in the same class of compounds". It is not clear, what is meant by the "class of compounds" in the context of the recited method. "Class of compounds" can be a very broad definition, such as class of organic acids, salts, amines, inorganic compounds, etc. All compounds belonging to the same class can have completely different behavior in the same process. The term "the same class of compounds" is not a definite and clear term. Moreover, it is not apparent, if these compounds all participate in the same process, or if they give the same product, etc. The compounds belonging to the same class of compounds are characterized by a common group control ID. However, in the last step of the claim the same group control ID is characterized as the common number for controlled compounds having a predetermined common component. Does it mean that "the same class of compounds" recited previously comprises controlled compounds having the same predetermined component? If this is the case, it is not clear, why the class of the compounds is

Art Unit: 1743

not defined in this way in the beginning of the claim, which leads to confusing double definition of ID in the claim?

Moreover, it is not clear how different controlled substances comprising the same component can simultaneously participate in the process? No examples of such process were provided in the specification. For example, it is not apparent as to what would be the process, in which several types of zinc compounds are participated? The description of the “same class of controlled compounds” participating in the same process is not adequately provided by the specification, and therefore lacks clarity and definiteness.

Since it appears that a toxic or harmful component of a material to be used in a process is controlled and monitored, the examiner considers any material comprising such component, which can be a single compound, or an element as meeting the requirement of the independent claims. In other words, it is a specific compound under control, which is provided with a unique ID number independent on what material it is a part of. For example, benzene is getting a unique ID number, since there are no other elements of the same class, which would share a common component with benzene. This leads to a definition of controlled compounds with each of the compounds assigned a unique ID. No examples for several different substances comprising the same component participating in the same process were disclosed in the specification.

Furthermore, while the first three steps are obviously business type method steps, the fourth step of the amended claim 1 is related to the real process involving real components and real analysis. In order to perform the fourth step, providing chemical materials to be used in the process should be recited in the claim. On the other hand, if the materials provided in the process are known, then it is not clear as to why should they be analyzed, since the amount of starting material is usually known before the process is performed? Also, it is not clear from the forth step, if the controlled substances are not transformed during the process, since it appears that the same control substances comprise the starting materials and products? Since the amount of starting materials (involving those that are in the controlled group) are conventionally known, the step is considered to be inherent to any process involving transformation of starting materials. Claims 7, 12 and 39 have the same deficiency.

Claims 3, 9 and 15 are not clear as to what “the source of control” might be, and how it is related to all other data sets of the parent claims; therefore, it is not apparent, what is a control

Art Unit: 1743

object code. If the “source of the control” is an outside organization, then it is not clear as to how is it possible to perform this step by any practitioner in the art, if it is under the control of the outside organization?

Claim 6 recites “obtaining said data sets from an outsourcing company”, while the parent claim recites “providing data sets”. If “providing data sets” means “obtaining said data sets from outsourcing company”, does it mean that this should be the outsourcing company that provides these data? If this is the outsourcing company that provides the data, then how can the steps of the parent claim be active steps performed by the routineer in the art?

Claim 14 recites “information about said controlled substances”. “Information” in this context is too broad and indefinite term. Which type of information is meant here? Is it relevant to the toxicity of the compounds? Their structural formulas? The claim is indefinite, since “information” is not a definite term in the context of the claim.

Since no clear and unambiguous definition of the “class of compounds” is provided by the specification, and since such class of compounds can comprise just one compound, if there are no other compounds, which constitute the material and belong to the same class, the examiner interprets the term “the same class of compounds” as the class, which can comprise just one component, with ID assigned to one compound.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-12, 14-17 and 39** are rejected under 35 U.S.C. 102(b) as being anticipated by Sturgeon et al. (US 5,664,112).

Sturgeon teaches a method of integrated Hazardous Materials Management (HMM), providing database for materials containing hazardous compounds and grouping controlled (hazardous) substances by Hazardous Materials Index. “The HMM grouping 21 monitors

consumption of chemicals and chemical mixtures, using process definitions and using manual drawdown for non-process consumption. Process definitions cover all chemicals used as input materials for a given process. Process templates provide users with reusable process definitions and with process run parameters such as process run date and frequency of use. Chemical emissions, outfalls and by-product wastes are tracked as they arise by the HPM [Hazardous Permit Management] and HWM [Hazardous Waste Management] groupings 31 and 51. The HMM grouping 21 can generate in-house chemical transfer and usage reports and mass balance reports" (col. 12, lines 21-31). Process templates intrinsically provide ratio of discharge and emission quantity of hazardous compounds. HMM includes handling precautions, hazards and legal regulations with the databases provided by an outsourcing company (Figures 1-2). The amounts of starting materials including hazardous compounds are inherently known for every performed process.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1743

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1-12, 14-17 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Leal et al. (US 5,311,437, IDS).

Leal teaches a method for management of chemical materials, comprising providing data sets containing controlled (hazardous) substances, "identification of the physical character of the material, identification of a procedure in which the material is operable, and a hazard/environmental assessment. The selector tool further includes selection means executable by the digital processor for controllably selecting, and optionally displaying in a pre-selected manner that is useful in making a materials selection decision, a material from the data base responsive to a comparison with the physical character of the material, the procedure identification, the end-product specifications, the product/performance risk, or the hazard/environmental assessment. The selection may also be made on other factors such as end product specification and product performance risk" (col. 2, lines 43-59). The amounts of the hazardous materials used as starting materials in the process are inherently known.

While Leal does not specifically indicate grouping compounds and providing them a common control group ID, it would have been obvious for any person of ordinary skill in the art to do so, because it helps manage compounds with e.g. the same toxicological properties. While Leal does not specifically indicate a control object code for designating the source of control, it would have been obvious to do so, because this facilitates managing manufacturing facilities.

Response to Arguments

11. Applicant's arguments filed 03/08/06 have been fully considered but they are not persuasive.

The Applicants refer to definition of the "same class of compounds" in the specification of the publication, i.e.

Art Unit: 1743

“[0058] The substance group control number 205 is the control number of substances under control which is appointed by the control object group, and the substance under control belonging to the same substance group has the same substance control number. For example, if a substance under control which is generally called "xxxx compound" like zinc compound has a substance group control number 1, then all the substances belonging to "xxxx compound", that is, zinc chloride, zinc oxide, and diethyl zinc belonging to zinc compounds are given the same substance control number 1. In other words, the substance under control is categorized by a group control number and the number is the same for substances in the same "group" or "compound." [0059] Also, this substance control number 205 is designed for control by giving the same identifying information to the substance under control belonging to the same substance group. The identifying information may be numerals shown in FIG. 4 and any letters, alphabet, or signs”.

The examiner cannot consider such definition clear and unambiguous. While the example with zinc makes it more apparent as to what the Applicants were meant to state, the definition itself is very confusing. If the Applicants wanted to indicate that the control number is assigned to the compounds with a common component, this should have been clearly stated in the specification. The definition of the “same class of compounds” provided in the specification in its present form is unclear and indefinite.

The definition of the source of the control makes it unclear as to what is the active step of the claim. If “the source of control” is supposed to provide a control object code, then it is not clear as to how is it possible to perform this step by any routineer in the art, if it is not under control of the practitioner of the method?

Regarding claim 6, if the Applicants’ explanation of claim 6 results in the interpretation of the parent claim the way it is provided in the remarks, the issue of enablement arises for the parent claim; the method, which comprises steps, which are supposed to be performed by an outside organization, rather than a routineer in the art, cannot be considered enabled for any routineer in the art, since they are not under his/her control.

Regarding claim 14, while some examples of information about the controlled substances are provided in the named paragraphs of the specification, the term “information” cannot be considered as clearly and definitely disclosed in the specification. “Information” should relate to specific properties of the compound, its chemical name, structure, etc.

Regarding rejection of the claims over the prior art, the examiner failed to find any examples in the specification, which described the same process with several different

Art Unit: 1743

compounds belonging to the “same class of compounds”. Mostly the compounds were single, such as benzene. No examples with several zinc compounds participated in the same chemical process were disclosed. Therefore, the “same class of compounds” comprising just one compound meets all the requirements of the pending claims, and Sturgeon covers the subject matter of the indicated claims. Moreover, all starting materials used in the process are known upfront, including their amounts. If benzene is used as a hazardous material in a process, its quantity is well known. Moreover, it comprises “the same class of compounds”, since there are no other materials, which share the same component with benzene.

In their arguments related to Leal’s reference, the Applicants again refer to the example with zinc ions, which are supposedly result from the same process using different zinc compounds. The examiner respectfully requests the Applicants to provide a reference to the part of the specification, which discloses utilizing several different zinc compounds with different properties, toxicity, reactivity, etc., which were used in the same process. The examiner failed to find such process. If several zinc compounds are used in different processes, while still having unique assigned ID number, then the recitation of the claims should be different.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/22/06

A handwritten signature in black ink, appearing to read 'Yelena Gakh', is positioned above the printed name.

**YELENA GAKH
PRIMARY EXAMINER**